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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/558,576 04/26/00 WHITSETT M.D.

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020995 HM22/0221  
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EXAMINER

ROBINSON, P

ART UNIT

PAPER NUMBER

1653

DATE MAILED:

02/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.

09/558,576

Applicant(s)

WHITSETT M.D., JAMES

Examiner

Patricia A. Robinson

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2000.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 10 and 29-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10 and 29-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) Z.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group IV (Claim 10) drawn to pharmaceutical compositions comprising SP-D protein in Paper No. 6 is acknowledged.

### ***Response to Amendment***

The amendment filed in Paper No. 6 on 12/18/2000 was received, entered and considered.

Based on the aforementioned amendment, claims 1-9 and 11-28 are cancelled per instructions on Page 3 last paragraph. New claims 29-34 were added.

Claims 10 and 29-34 are pending in the instant application and are examined in herein.

### ***Priority***

This is a Continuation-in-Part that claims priority to PCT US99/24675 filed October 20, 1999, which claims priority to 60/104941, filed October 20, 1998. Thus, the common subject matter receives priority back to 10/20/1998.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application

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by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 10, and 30-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Taeusch (US Patent 6,180,142 B1).

Taeusch teaches the treatment of pulmonary diseases using a composition containing SP-A, SP-B, SP-C or SP-D individually or in combination in humans. (See Col. 1, line 56 – Col. 2, line 20; Col. 2, lines 38-43; and Col. 4, lines 2-9) (Claims 10, 30-32).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10, 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taeusch in view of Ariizumi et al.

Taeusch teaches the treatment of pulmonary diseases using a composition containing SP-A, SP-B, SP-C or SP-D individually or in combination in humans. (See Col. 1, line 56 – Col. 2, line 20; Col. 2, lines 38-43; and Col. 4, lines 2-9) (Claims 10, 30-32 and 34).

Taeusch does not teach the use of IL-4 in the composition, however the Ariizumi et al. reference does. Ariizumi teaches that the C-type lectins family includes the pulmonary surfactant proteins. (See Col. 2, lines 3-6). Arrizumi et al. also teaches pharmaceutical compositions containing the C-type lectins. (See Col. 77, lines 36-53). Finally, Ariizumi

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et al. teaches the use of adjuvants to enhance the effectiveness of C-type lectin compositions, and in particular IL-4. (See Col. 47, lines 49-55)(Claims 29 and 33).

Thus, where Taeusch does not teach the use of IL-4 in the pharmaceutical composition, it would have been obvious to one of ordinary skill in the art to have modified Taeusch by using the teachings in Ariizumi et al. to further enhance the efficacy of the pharmaceutical composition. These references when combined teach all of the claimed invention. Therefore, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

### **Conclusion**

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Robinson whose telephone number is 703-305-0096. The examiner can normally be reached on 8:00 - 4:30 Monday - Friday, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 703-308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.



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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

PAR  
February 19, 2001

A handwritten signature in black ink, reading "Karen Cochrane Carlson" followed by a stylized monogram or initials.

KAREN COCHRANE CARLSON, PH.D  
PRIMARY EXAMINER